UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456
	CIVIL ACTION: 01-CV-12257-PBS
THIS DOCUMENT RELATES TO 01-CV-12257-PBS AND 01-CV-339	Judge Patti B. Saris

PLAINTIFFS' OBJECTIONS AND RESPONSES TO BMS'S CONTENTION INTERROGATORIES TO PLAINTIFFS

GENERAL OBJECTIONS

1. (a) Plaintiffs object to each of these interrogatories on the grounds that they constitute contention interrogatories that are premature. Contention interrogatories are "more appropriate after a substantial amount of discovery has been conducted." *McCarthy v. Paine Webber Group, Inc.*, 168 F.R.D. 448, 450 (D. Conn. 1996) (citing *Fischer and Porter Co. v. Tolson*, 143 F.R.D. 93, 95 (E.D. Pa. 1992). Although contention interrogatories are allowed, "plaintiffs are generally excused from responding to defendants' contention interrogatories until they have completed a substantial amount of discovery, particularly document inspection." *Bonilla v. Trebol Motors Corp.*, 1997 WL 17844 *65 (D. Puerto Rico 1997).

(b) Courts have held that it is up to the party serving contention discovery to justify its use during the discovery period:

> A party filing contention interrogatories early in the pretrial period, before substantial documentary or testimonial discovery has been completed, has the burden of justification. It must present "specific, plausible grounds for believing that securing early

> answers to its contention questions will materially advance the goals of the Federal Rules of Civil Procedure."

Fischer and Porter Co. v. Tolson, 143 F.R.D. 93, 96 (E.D. Pa. 1992) (citing *In re Convergent Technologies Sec. Litig.*, 108 F.R.D. 328, 338-339 (N.D. Cal. 1985). In this case, contention interrogatories are particularly premature given the lack of discovery and are especially inappropriate considering defendants' refusal to fully comport with CMO No. 10.

2. (a) Certain of the interrogatories go to the issue of damages. As set forth in the AMCC, a central issue in the present action is whether AWPs for defendants' drugs bear some relationship to the actual cost or wholesale price. It is premature to require plaintiffs to calculate how much they should have paid for AWPIDs or a precise damage methodology while defendants have not yet allowed them to learn how the drugs were priced.

(b) In order for the plaintiffs to fully comply with their obligations under Rule 26(a)(1)(C), defendants must first provide them with the opportunity to do so. *See* Comments to Fed. R. Civ. P. 26(a)(1)(C) ("[A] party would not be expected to provide a calculation of damages which ... depends on information in the possession of another party or person." *See also Kleiner v. Burns*, 2000 WL 1909470 (D. Kan. 2000); *City and County of San Francisco v. Tutor-Saliba Corporation*, 218 F.R.D. 219, 222 (N.D. Cal. 2003) (refusing to mandate disclosure of detailed calculation of damages, in part, "given that many of the documents which are likely to inform the calculation remain in defendants' hands"). No opportunity has yet occurred in this case.

(c) Federal courts routinely allow parties to consult with experts prior to making a full disclosure of their damage computations or methods under Fed. R. Civ. P. 26(a)(1)(C). *See, e.g., Pine Ridge Recycling, Inc. v. Butts County, Georgia*, 889 F. Supp. 1526,

1527 (M.D. Ga. 1995) (denying the motion to exclude evidence of the plaintiff's claimed damages under Fed. R. Civ. P. 26(a)(1)(C) where the "method of computation ... ***will necessitate expert testimony***, which is not due until later this year") (emphasis added); *City and County of San Francisco*, 218 F.R.D. at 222 (refusing to mandate disclosure of detailed calculation of damages, in part, because "some type of ***expert analysis may be required***" (emphasis added).

3. Plaintiffs reserve the right to supplement these responses as discovery proceeds in this case. Plaintiffs also note in this regard that defendants have in many instances not produced relevant documents, thus it is premature to supply answers to many of the requests.

4. All responses provided herein are made subject to, and without waiving, these general objections.

RESPONSES

1. State what you contend is the proper definition of AWP, as that term is used in the AMCC, and identify any statute, regulation or authority that supports that definition.

ANSWER: *See* General Objection 1. Notwithstanding the foregoing objection, plaintiffs state at this time the following: "AWP" means average wholesale price, a term capable of plain meaning, industry and statutory interpretation and definition. The average wholesale price is the most commonly used benchmark to set reimbursement or endpayor prices for prescription drugs in the United States, both in the private sector (for oral pharmaceuticals distributed in the pharmacy and mail order channels, as well as for injectibles and other drugs in the provider administered channel) and in the public sector (under the Medicare Part B program and under Medicaid). For covered drugs and biologicals, Medicare Part B generally reimburses at "95 percent of average wholesale price." 42 U.S.C. 1395u(o). AWP is intended to estimate an

average price at which dispensers (such as pharmacies or physicians) purchase a drug at wholesale. As a result, private and public sector endpayers use AWP as a benchmark for cost reimbursement, and each year AWP is used as the benchmark price to effectuate many billions of dollars of public and private drug reimbursement. AWP, as the term and practice shows, reflects an administratively efficient, reasonable basis upon which to reimburse dispensers (typically pharmacy or physician) for the cost to the dispenser of purchasing a drug product.

Traditionally, AWP has been based on prices reported by drug manufacturers and published in compendia such as the Red Book. However, manufacturers and wholesalers increasingly give physicians and providers discounts that reduce the actual amount that the physician or provider actually pays for the drugs. These discounts are not reflected in the published price and reduce the amount providers actually pay to levels far below those prices published in industry publications. Furthermore, use of the AWP, as reported by manufacturers to companies which compile such prices, creates a situation where a manufacturer can, for certain drugs, increase the reported AWP and, in turn, offer physicians and others in the distribution chain a deeper discount. Authority for this definition is found in the April 2003 Report of the Office of the Inspector General.

In addition, CMS Administrator, Thomas Scully, identified a definition that reflects a common understanding of AWP, namely that "AWP is intended to represent the average price at which wholesalers sell drugs to their customers, which include pharmacies and physicians." This definition is consistent with similar definitions in the marketplace. For example, Express Scripts 10-K (Dec. 31, 2001) defines AWP as:

> AWP is a standard pricing measure used throughout the industry as well as by us as the basis for calculating drug prices under our

> health plans and pharmacies and rebates with pharmaceutical manufacturers.

GSK defines AWP as:

> Average Wholesale Price (AWP): The composite wholesale prices charged on a specific commodity that is assigned by the drug manufacturer and is listed in either the Red Book or Blue Book and ***used by third-party payers as a basis for reimbursement***.

(GSK-MDL-ZN02-035985)(AMCC Para. 379).

Authority for these definitions is found in the references cited above.

2. State whether you contend that the existence of a "spread" as that term is used in the AMCC, without more, violates the law, and if not, identify the additional conduct that you claim give rise to a violation.

ANSWER: *See* General Objection No. 1. The term "without more" is so vague as to render this interrogatory meaningless. For example, a spread of 1,000% does not exist in isolation. The "more" includes a published AWP that disguises the real average wholesale price. Many other factors potentially exist that constitute the "more" making this question "without more" too vague to answer.

3. State whether a spread, as that term is used in the AMCC, of any size violates the law, and if not, identify the size at which you contend a spread violates the law.

ANSWER: *See* response to Interrogatory No. 2. *See also* the Final OIG Guidance Office Of Inspector General, April 2003 wherein it states, "In other words, it is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the "spread" to induce customers to purchase its product"

4. Explain what you mean by the phrase "marketing the spread" as it is used in the AMCC.

ANSWER: *See* General Objection No. 1. Subject to that objection, *see, e.g.*, AMCC ¶¶ 3-7, 133-78, 339, 345 and 347. *See also* response to No. 3.

5. Identify each act that constitutes marketing the spread as that phrase is used in the AMCC.

ANSWER: *See* General Objection No. 1. Plaintiffs object to the phrase "identify each act" for in the context of this case there are likely hundreds if not thousands of such acts the precise identity of which is hidden in defendants' own files and known by defendants' employees and to which plaintiffs do not have access. The AMCC identifies examples of marketing the spread.

6. Explain what you mean by the phrase "manipulating the spread" as it is used in the AMCC.

ANSWER: *See* General Objection No. 1. *See* Response No. 3. The "spread" is the difference between the amount a customer pays for a product and the amount the customer receives upon resale of the product to the patient or other payer. In many situations under the federal programs, pharmaceutical manufacturers control not only the amount at which they sell a product to their customers, but also the amount those customers who purchase the product for their own accounts and thereafter bill the federal health care programs will be reimbursed. To the extent that a manufacturer controls the "spread," it controls its customer's profit.

Manufacturers' reported prices should accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers. To the extent reported prices are not accounting for the foregoing, a manipulation of the spread has occurred. *See also* The

Final OIG Guidance Office of Inspector General, April 2003 wherein it states, "If a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers' profits by increasing the amount the federal health care programs reimburse its customers, the anti-kickback statute is implicated. Unlike bona fide discounts, which transfer remuneration from a seller to a buyer, manipulation of the AWP transfers remuneration to a seller's immediate customer from a subsequent purchaser (the federal or state government). Under the anti-kickback statute, offering remuneration to a purchaser or referral source is improper if one purpose is to induce the purchase or referral of program business."

7. Identify each act that constitutes manipulating the spread as that phrase is used in the AMCC.

ANSWER: *See* General Objection No. 1. To the extent you contend that plaintiffs must specify "each act," such a contention interrogatory is overbroad and premature as it would require plaintiffs to comb through thousands of documents many of which have not yet been produced and to cull through testimony that has not yet been provided. To the extent BMS seeks a description of the practices in general they are set forth in the AMCC as well as in the TAP's indictments and guilty plea.

8. State whether you contend that it violates the law for a manufacturer to submit a wholesale acquisition cost to a publisher that reflects the actual price that the manufacturer charges to wholesalers.

ANSWER: *See* General Objection No. 1. Plaintiffs do not contend that it is a violation of the law for a manufacturer to submit a WAC that reflects actual prices charged wholesalers. However, in instances where AWP is determined from WAC, it is unlawful to submit a WAC that does not include in its calculation, rebates, discounts, chargebacks, free

goods, special offers and any other incentive that impacts the actual average price paid by a wholesaler, hospital, physician, or purchasing group acting as a wholesaler. The importance of accurate price reporting was recently reconfirmed by the Office of the Inspector General ("OIG") in an April 2003 report: "Compliance Program Guidance for Pharmaceutical Manufacturers." The OIG report found that the "government sets reimbursement with the expectation that the data provided are complete and accurate." The OIG report made it clear that the AWP must be a meaningful figure that is not artificially inflated:

> Where appropriate, manufacturers' reported prices should accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers. Any discount, price concession, or similar benefit offered on purchases of multiple products should be fairly apportioned among the products (and could potentially raise anti-kickback issues). Underlying assumptions used in connection with reported prices should be reasoned, consistent, and appropriately documented, and pharmaceutical manufacturers should retain all relevant records reflecting reported prices and efforts to comply with federal health care program requirements.

9. State whether you contend that it violates the law for a manufacturer to offer chargebacks, discounts or rebates to wholesalers, retailers, PBMs, GPOs, providers or payors.

ANSWER: Plaintiff objects to this interrogatory on the grounds that it is overbroad. For example, discounts or rebates may violate state or federal antitrust laws. They are not the subject of this lawsuit. In the context of AWP litigation, plaintiffs have outlined in the AMCC the circumstances under which the use of chargebacks, discounts, rebates, etc. violate the laws cited in the AMCC. These circumstances include any situation where a manufacturer has caused to be published a WAC, WLP, NDP, list price and/or an AWP, which did not reflect such offers.

10. State whether you contend that a manufacturer is required to offer the same discount to every purchaser of prescription drugs.

ANSWER: No such contention is made.

11. State whether you contend that a manufacturer is required to publicly disclose every chargeback, discount or rebate that it offers to purchasers of prescription drugs.

ANSWER: No. However, the chargebacks, discounts or rebates must be reflected in the manufacturer's reported prices, submitted to industry publishers, if the manufacturer knows that WAC, NDP or WLP is being used to calculate AWP, or if the manufacturer reports AWP itself.

12. State whether individuals who pay cash at retail pharmacies, and are not members of the Together Rx program, are members of any class or subclass for which you intend to seek certification in this case.

ANSWER: Yes.

13. State whether hospitals are members of any class or subclass for which you seek certification in this case.

ANSWER: Yes, if the hospital purchased for its own use based on AWP. Further, the prices at which hospitals purchase drugs are relevant in determining AWP, WAC, NDP and WLP.

14. Explain what you mean by the phrase "price calculated by reference to the published AWP" as it is used in the definition of the AWP payor class in the AMCC.

ANSWER: The words mean exactly what they say. *See also* definition of AWP by GSK referred to in response to No. 1.

15. State whether you are asserting any claims on behalf of payors who purchase prescription drugs from retailers without utilizing the services of a PBM.

ANSWER: Yes.

16. State whether you are asserting any claims on behalf of beneficiaries or participants of payors on whose behalf you are asserting claims.

ANSWER: Yes, to the extent they paid a graduated co-pay that would be affected by a change in the AWP they are.

17. Set forth what you contend is the proper measure of damages in this case.

ANSWER: *See* General Objections, as well as Judge Stearns' order denying similar interrogatories in *In re Lupron Marketing and Sales Practices Litig.*, dated March 1, 2004. The AMCC itself discloses plaintiffs' theory of damages:

> 3. More specifically, the Defendant Drug Manufacturers report to trade publications a drug price – the Average Wholesale Price (or "AWP") – that for many drugs is deliberately set far above the prices that these drugs are available in the marketplace. The AWPs for these drugs are deliberately false and fictitious and created solely to cause Plaintiffs and the Class members to overpay for drugs. Because all drugs administered under Medicare Part B are priced based on the published AWPs, the Defendant Drug Manufacturers inflate AWP reimbursement rates to enable providers and others to make secret profits through overcharges to patients, their insurers and other end payors. This, in turn, motivates the providers to sell and administer the drugs with the most inflated AWPs, resulting in increased market share and profit for the Defendant Drug Manufacturers and inflated payments for drugs by individual patients (through co-pays or direct payments), health plans and insurers.
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> 139. Plaintiffs and the members of the Class paid for the drugs based on the inflated AWPs reported by the Defendant Drug Manufacturers.

> 140. The Defendant Drug Manufacturers' pattern of fraudulent conduct in artificially inflating the AWPs for their drugs (sometimes referred to herein as the "AWP Scheme") directly caused Plaintiffs and the members of the Class to substantially overpay for those drugs.
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> 196. Thus, each Defendant concealed that (i) its AWPs were highly-inflated (and were inflated solely to cause Plaintiffs and the Class to overpay for the AWPIDs), (ii) it was manipulating the AWPs of the AWPIDs, and (iii) the AWPs bore no relationship to the prices paid for, or the pricing structure of, the AWPIDs as they were sold to providers and others.
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> 541. Plaintiffs and other Third-Party Payors who are members of the class reimburse health care providers for pharmaceuticals based upon the published AWP for brand name drugs and based upon MAC, for generic drugs, which in turn is derived from AWP. Accordingly, plaintiffs and Third-Party Payors are directly damaged by fraudulent AWP pricing schemes for drugs covered by employee health and benefit plans. By virtue of the fact that AWP is the reimbursement benchmark for pricing of the AWPIDs at issue, such injury occurs in all aspects of the distribution chain for the AWPIDs, including the PBM segment, non-PBM purchases, Part B covered drugs and non-Part B covered drugs.

18. State whether you are prepared to pay for the expense of personalized notice to any class member whose name and address can be ascertained and, if so, identify the source and amount of funds available for that purpose.

ANSWER: Plaintiffs will propose the type and manner of appropriate notice when they file their motion for class certification. The source of payment is not calculated to lead to discoverable information and therefore the interrogatory is improper. It is also premature since the exact size and scope of the class and manner of notice is not yet known.

DATED: June 17, 2004.

By /s/ Steve W. Berman

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CERTIFICATE OF SERVICE

I hereby certify that I, Steve W. Berman, an attorney, caused a true and correct copy of the foregoing Plaintiffs' Objections and Responses to BMS's Contention Interrogatories to Plaintiffs to be served on all counsel of record electronically on June 17, 2004, pursuant to Section D of Case Management Order No. 2.

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